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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	93004	2429
21901	7590	11/29/2005	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,518

Applicant(s)

JAROSZESKI ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,8,10,21,22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8,10,21,22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Action is in response to the communication filed on 9/14/2005. The amendment filed 9/14/2005 is acknowledged and has been entered. Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are currently pending in the application and are addressed herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 6, 8, 10, 21, 22 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

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MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claims 1, 21 and 24 have been amended to include the limitation “of about 200V/cm or less” which is considered new matter (emphasis added). Claims 2, 4, 6, 8, 10, 22 and 23-28 are dependent claims that also encompass the new matter limitation. It is pointed out that “about 200V/cm” is not limited to 200V/cm, rather it encompasses some range around 200V/cm that includes embodiments greater than and less than 200V/cm. Looking to the specification for support, explicit support was found for the following parameters: field strengths between 1mV/cm and 200V/cm (i.e., .001V/cm-200V/cm), wherein the duration of the pulse is in the range of 0.1s to 20 minutes, with 100ms to 100s duration being a preferred range (see page 6, lines 6-9); 1mV/cm-400V/cm, 1mV/cm-500V/cm, 1mV/cm-800V/cm (Table 1 on page 7); 10V/cm for 1 sec (Table 2 on page 8); 50V/cm for 200ms, 100V/cm for 200ms (Table 3 on page 9); and 20V/cm for 1 s (Table 4 on page 10). The specification does not appear to have either explicit or implicit support for “about 200V/cm or less”. Applicants, indicate in the communication filed 9/14/2005 that support for the limitation “about 200V/cm or less” can be

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found in paragraph [0020] (see page 5 of the communication filed 9/14/05). However, paragraph [0020] only discloses field strengths between 1mV/cm and 200V/cm. The disclosure of paragraph [0020] does not provide support for “about 200V/cm” because it only contemplates field strengths in the range of 1mV/cm-200V/cm and does not contemplate field strength of “about 200V/cm”. Furthermore, there does not appear to be support in the specification for any field strength below 1mV/cm.

Additionally, to the extent that the claimed compositions and/or methods are not described in the instant disclosure, the instant claims are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

It is noted that amending the claims such that they were limited to an electric field having a field strength in the range of 1mV/cm to 200V/cm would obviate the instant rejection under 35 USC 112, 1st paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 8, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann et al. (U.S. Patent 6,055,453, published April 25, 2000; previously cited).

It is noted that Hofmann was previously cited as the basis for a rejection under 35 USC 102(b), but the rejection was subsequently withdrawn. However, upon further consideration and closer examination of Hofmann, it was concluded that Hofmann does teach a method which is encompassed by the instant claims. That is, Hofmann does teach a method of delivering a molecule into a cell in a tissue wherein the method "consists essentially of" introducing a molecule into a target tissue and applying a single electric field of about 200V/cm or less and for a duration of 100ms. As such, Hofmann does anticipate the instant claims.

Specifically, the instant claims are drawn to a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of the steps of: introducing a molecule into a target tissue comprising a cell; applying an electric field to the target tissue, the application of the electric field consisting of a single continuous electric field of about 200V/cm or less applied for a duration of 100ms to 20 minutes; and effecting a change in porosity of the cell in response to the application of the electric field sufficient to facilitate entry of a desired molecule into an interior of the cell (claim 1); wherein the duration of the applying step is in a range of 100ms to 100sec (claim 2); wherein the electric field comprises a square wave pulse (claim 6); wherein the introducing step is by syringe injection (claim 8); and wherein the target tissue is skin, tumor, muscle, ovary, prostate, lung, heart, kidney, colon, testis, melanoma, etc. (claim 10).

Hofmann teaches a method for facilitating a delivery of a desired molecule such as nucleic acids, antisense nucleic acids, Ribozymes, polypeptides, and polynucleotides into a target tissue comprising a cell (see col. 12, lines 14 and 34; col. 13, lines 13, 24 and 31-31); and applying a single continuous electric field to the target tissue for a duration sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of a cell (for example, see column 10, lines 3-56; and col. 11, lines 63-65). Hofmann explicitly teaches that there can be any “number of desired pulses, typically one to 100 pulses per second.” (see column 10, lines 12-13). Hofmann explicitly teaches that the electric field can have a field strength comprising 10V/cm-20kV/cm and can be applied for a duration of 10 μ s-100ms (see col. 10, lines 3-41). It is noted that the upper limit of the duration taught by Hofmann (100ms) is encompassed by the instant claims which require a pulse for a duration of 100ms to 20 minutes.

Hofmann teaches that the electric field can be, for example, a square pulse waveform (see col.10, line 55-56).

Hofmann teaches that the introducing step can be by needle injection (i.e. syringe) (see col. 13, lines 31-45).

Hofmann also teaches that the target tissue can be skin, tumor, muscle, ovary, prostate, lung, heart, kidney, colon, testis, melanoma, etc. (see col. 14, lines 10-30).

Therefore, Hofmann meets all of the limitations of the instant claims. Thus, the instant claims are anticipated by Hofmann et al.

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It is noted that Hofmann does not teach applying the pulse for a duration of longer than 100ms. As such, amending the claims such that they are limited to applying the pulse for a duration of 200ms to 20 minutes would obviate this rejection.

Response to Arguments

Applicant's arguments filed 9/14/2005 have been fully considered.

Applicant's arguments filed 9/14/2005, with respect to the rejection(s) of claim(s) under 35 USC 112, 1st paragraph, 35 USC 102(e) and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amendment to the claims (new matter) and in view Hofmann et al. (35 USC 102(b)) for the reasons indicated herein.

Conclusion

No claim is allowed.

Since this Office Action re-introduces a rejection based on Hofmann et al. which was previously withdrawn, the instant rejection is made Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
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Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER